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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,436	01/20/2004	Hans J. Hoorn	SYN-0018A	1153

38427 7590 01/23/2007

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EXAMINER	
CHANG, CELIA C	
ART UNIT	**PAPER NUMBER**
1625	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,436	HOORN ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-44* is/are pending in the application.

4a) Of the above claim(s) *23-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group II in the reply filed on Oct. 30, 2006 is acknowledged. The traversal is on the ground that restriction solely dependent on different classification is improper. This is not found persuasive because please note that group I assaying method does not require any limitation on what method, procedure or limits of detection must be while group II is a business method in making a decision based on a "required" upper or lower limitation of certain data for which a limited, reproducible and having a required measurement sensitivity must be used so that consistent decision can be made. Therefore, the two groups although both employing assay method, do not share the same scope. Further, group I method has utility of its own in detecting the existence of N-formyl paroxetine such as using TLC while group II does not require the subcombination of group I because group II can be practice with HPLC because only HPLC gives sufficient sensitivity for the low concentration required to measure.

The requirement is still deemed proper and is therefore made FINAL.

Claims 27-44 are prosecuted. Claims 23-26 are withdrawn from consideration. However, in the event the scope of the two groups are made identical, the combination/ subcombination can be rejoined.

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 27-30, 36-37, 41 and 43 are rejected under 35 U.S.C. 101 because the claims are drawn to inoperable process.

Please note that the claims are drawn to process wherein the assaying procedure has no limitation thus including all past and future analytical methods. In addition, the process cannot be operated when unlimited assaying method is employed. That is, if a method of measuring N-formyl paroxetine has the sensitivity or limitation of detecting 5% and above of this compound,

then, every lot will pass the test because the method can never provide data for the required decision.

For the method of claims 27-30, 36-37, 41 and 43 to operate, the explicit assaying procedure must be incorporated together with the necessary upper limits of N-formyl paroxetine content.

3. Claims 27-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, as well as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention; nor as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

On pages 21-24 of the specification a method of assaying and releasing manufactured lot of paroxetine with assaying the N-formyl paroxetine impurity by TCL or HPLC. Nowhere in the specification that other analytical method would provide a measurement limit that will detect less than 0.3% of the N-formyl compound i.e. the upper permissible limit for release. The specification provided no description as to what other method with what other limits and how such broadly encompassed all process and limits can be operated.

The scope of description and enablement is therefore, limited to TLC or HPLC assaying method with upper limits of release being 0.3%.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avrutov et al. US 2003/0083501 (effective filing date Jun.14, 2001).

Determination of the scope and content of the prior art (MPEP §2141.01)

Avrutov et al. '501 disclosed method of purifying paroxetine to rid the pink color of the product, see whole article. Particularly, the product was assayed for purity by HPLC to contain less than 0.02% impurity.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art is that the pink impurity was not identified. In view of the upper limit of impurity is 0.02%, (see page 4, section [0043]) which is less than the upper limits of the instant specification 0.03%, then, even if all of the impurity are formyl compounds, the impurity level still fall within the instant claims.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art would be in possession of the claimed process since the decision on release of a manufactured lot is not on "what" or "how much" is the impurity but on the purity of the drug. The prior art provided assaying procedure rendered the instant procedure obvious **because** the same HPLC steps were employed and the same desirable purity of the drug was obtained. It is immaterial whether the impurity is named by its chemical name or by its color or other characteristic, since impurity is among the colored fraction of the analytical procedure.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jan. 17, 2007

Celia Chang
Primary Examiner
Art Unit 1625